

Amendment and Response
Applicants: Rudy Mazzocchi et al.
Serial No.: 10/051,591

Attorney Docket: MVA1001USC4

REMARKS

This is responsive to the outstanding Final Rejection issued January 4, 2005. Claims 1, 4 – 19, 40 – 43 and 45 – 49 are pending. Claims 2, 3, 20 – 39, 44 and 50 – 56 are canceled. This Amendment and Response amends claims 1, 4, 40 and 45. Claims 5 – 19, 41 – 43 and 46 – 49 are original. The specification as filed supports all claims. The Office Action Summary lists claim 4 as rejected but there is no explanation of a rejection of record of this claim.

Applicant, Richard S. Kusleika, and Applicant's representative, Terry L. Wiles, thank Examiner Vy Q. Bui for the courtesy of a personal interview on February 3, 2005. At the interview a demonstration of the use of a guidewire and a balloon catheter to track over the guidewire was performed by Richard Kusleika, a representative of ev3 Inc., the assignee of the present invention. At the interview the differences between the claimed invention and the prior art were discussed and are set forth below. The present Amendment and Response is a *bona fide* effort to advance this application to issue.

Drawings

Applicants request the Examiner to acknowledge on the record that the drawings filed with this application are accepted or specifically note any objections thereto.

Information Disclosure Statements

The Form PTO-1449, submitted with an Information Disclosure Statement filed on June 12, 2003, has not been returned to Applicants. The Private PAIR database Image File Wrapper for this application does not reflect this Information Disclosure Statement. Attached hereto are copies of the Information Disclosure

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Statement filed on June 12, 2003, the accompanying Form PTO-1449, and the references cited thereon, together with a copy of the Auto-Reply Facsimile Transmission as proof of this facsimile transmission. The Examiner is requested to initial and date this Form PTO-1449 and return it to Applicants to confirm that the information cited thereon has been considered in the file of this application.

Rejection Under 35 U.S.C. § 102

Claims 1 – 3, 5 – 13, 16 – 22, 24 – 32 and 35 – 50 are rejected under 35 U.S.C. § 102(b) as being anticipated by GB-2020557 to Rüschi (“Rüschi”). The rejection of claims 2, 3, 20 – 22, 24 – 32, 35 – 39 and 50 is moot with the cancellation thereof. Applicants submit that, with the present amendments to independent claims 1, 40 and 45, Rüschi does not anticipate claims 1, 5 – 13, 16 – 19 and 40 – 49.

All of the claims as presently amended and supported by the specification require a filter element which is “self-expandable” (claim 1) or “radially expandable” (claims 40 and 50) from a collapsed configuration when the filter element is restrained to an expanded configuration when the filter element is unrestrained.” Additionally, method claims 40 and 45 each include a step of removing restraint on the filter element to “radially” expand the filter element. With respect to claims 40 and 45 Rüschi does not disclose any restraint, removal of which will allow the filter element to radially expand. With respect to claim 1 Rüschi does not disclose that the filter element is self-expandable. Rather, Rüschi requires the use a push/pull motion on the operating element 5 and the controlling element 4 to collapse/expand the diameter of the expandable element 6:

If, by pulling on the operating element, 5, the controlling element, 4 is moved relative to tube, 1, that is, if the controlling element, 4 is drawn out of the tube, 1, the end of the controlling element, 4, takes the head piece with it, so that the expandable element, 6, is expanded

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until it has attained approximately the form shown in Fig. 3. During this process, the shape of the mesh formed by the threads, 10, changes. If the head piece, 7, is further moved towards the tube, 1, the configuration of the expandable element, 6, represented in Fig. 4 is finally attained, the outer diameter of which is two- or several-fold the diameter of the non-expanded element, 6, (Fig. 1).

(page 4, lines 92-106, *inter alia*).

Accordingly, this rejection is unsupportable and must be withdrawn.

Additionally, Rüschi does not show or suggest a "guidewire," while all of the present claims require a "guidewire." A feature of the present invention is that the filter element is carried by a guidewire. In the context of the present application, the term guidewire is properly construed to mean an elongate component that can be used in combination with a number of medical devices, such as balloon catheters and atherectomy devices. In particular, these various other medical devices generally include a central or axial opening able to receive the guidewire, such that the medical device may be tracked along the guidewire from its free end towards its end within the patient's body, the guidewire acting as a guide for positioning the medical device. The guidewire may also act as a guide for the retraction and removal of the medical device after it has been used. See the present application at page 39, lines 14 – 21; page 43, lines 5 – 13; page 43, line 27 – page 45, line 28; *inter alia*. This construction of the term "guidewire" is consistent with the meaning understood by those of skill in the art. See, for example, the definition of guidewire in White, et al., *A Color Atlas of Endovascular Surgery*, J. B. Lippincott Co., Philadelphia, Pa., 1990, pages 26 – 27, a copy of which was included with the previous Amendment and Response, filed on October 11, 2004:

In general, guidewires are used to find and secure a pathway through the artery and the stenotic lesion. They pass well into the channel and act as a guide to the subsequent passage of therapeutic devices.

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Rüsch does not disclose a guidewire. Rüsch discloses a medical instrument having a controlling cable 4 that functions as a controlling or positioning element (Rüsch, page 2, lines 48 – 57). The Rüsch controlling element or cable 4 cannot be a guidewire, because an operating element is firmly attached to the controlling element 4 proximal end (Rüsch, page 4, lines 50 – 54), so that the operating element 5 may withstand pulling action to retract the controlling element 4 proximally (Rüsch, page 4, lines 92 – 99). In addition, a screw 3 protrudes radially. These structures would preclude the passage over cable 4 of other medical devices, such as balloon catheters and atherectomy devices.

Rejection Under 35 U.S.C. § 103

Claims 14, 15, 23, 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rüsch. Applicants understand this rejection as including the rejection of claim 4, inasmuch as claims 15, 23 and 34, also reciting nitinol for the filter element, are included in this rejection. The rejection of claims 23, 33 and 34 is moot with the cancellation thereof. This rejection does not set forth a sustainable finding of obviousness for these claims and is traversed.

The remarks concerning Rüsch regarding the previous rejection are repeated here as equally pertinent. Rüsch does not disclose or suggest the limitations of independent claims 40 and 45. Claims 4, 14 and 15 include additional limitations that further distinguish over Rüsch.

Accordingly, this rejection is unsupportable and must be withdrawn.

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CONCLUSION

In view of Applicants' present amendments to the claims and the remarks above, all of the claims are submitted to be in condition for allowance.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 3/4/05

By 

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